# MEMORANDUM

**TO:** Rosanne Mahaney – DMMA

**CC:** Dave Michalik - DMMA

**FROM:** Joyce Pinkett – DMMA

**DATE:** March 11, 2011

**SUBJECT:** LogistiCare Solutions Contract

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## LogistiCare Solutions Contract

This contract is the result of a Request for Proposal (RFP) No. HHS-10-091 issued by the Department of Health and Social Services and the Division of Medicaid and Medical Assistance on September 16, 2010. Following the bid opening and the selection process the committee recommended and you approved Logisticare Solutions as the successful bidder and the new contractor. This contract is effective April 1, 2011 through March 31, 2013.

As you know the Broker Model for the Medicaid non-emergency transportation (NET) program was developed as part of a cost containment measure and to increase efficiency. NET services are defined in the RFP as necessary non-emergency transportation services provided to Delaware Medicaid Assistance Program (DMAP) clients who have no other means of transportation. Necessary transportation is defined as the least expensive mode of transportation available that is appropriate to the medical and or functional needs of the client. NET service ensures reasonable access for DMAP clients to a medical service for the purpose of receiving treatment and/or medical evaluation.

The Division of Medicaid and Medical Assistance (DMMA) contracts with one Contractor to be responsible for the administration and provision of NET transportation in each of the three counties in Delaware to include wheelchair van, non-emergency ambulance, public transportation and car/station wagon, minivan services and mileage reimbursement. Non-emergency ambulance transportation is restricted to those clients who require transport by stretcher. The actual transportation services under the Contract and RFP is provided through subcontracts between the Contractor and transportation providers. The Contractor verifies client eligibility, coordinates trips, reimburses NET service providers and employs accountability measures to ensure effective utilization of services and expenditures. This administrative approach allows for the extensive coordination of trips and appropriate use of DMAP services and expenditures.

In the event that this contract is not authorized, DMMA will be required to obtain alternate methods to assure client transportation service.

# CONTRACT

A) Introduction

1. This contract is entered into between the Delaware Department of Health and Social Services (the Department), Division of Medicaid & Medical Assistance and the Division of Management Services (Divisions) and Logisticare Solutions, LLC (the Contractor).

2. The Contract shall commence on April 1, 2011 and terminate on March 31, 2013 unless specifically extended by an amendment, signed by all parties to the Contract. Time is of the essence. (Effective contract start date is subject to the provisions of Paragraph C 1 of this Agreement.)

B) Administrative Requirements

1. Contractor recognizes that it is operating as an independent Contractor and that it is liable for any and all losses, penalties, damages, expenses, attorney's fees, judgments, and/or settlements incurred by reason of injury to or death of any and all persons, or injury to any and all property, of any nature, arising out of the Contractor's negligent performance under this Contract, and particularly without limiting the foregoing, caused by, resulting from, or arising out of any act of omission on the part of the Contractor in their negligent performance under this Contract.

2. The Contractor shall maintain such insurance as will protect against claims under Worker's Compensation Act and from any other claims for damages for personal injury, including death, which may arise from operations under this Contract. The Contractor is an independent contractor and is not an employee of the State.

3. During the term of this Contract, the Contractor shall, at its own expense, carry insurance with minimum coverage limits as follows:

| | | |
|---|---|---|
| | a) Comprehensive General Liability | $1,000,000 |
| and | | |
| | b) Medical/Professional Liability | $1,000,000/ $3,000,000 |
| or | c) Misc. Errors and Omissions | $1,000,000/$3,000,000 |
| or | d) Product Liability | $1,000,000/$3,000,000 |

All contractors must carry (a) and at least one of (b), (c), or (d), depending on the type of service or product being delivered.

If the contractual service requires the transportation of Departmental clients or staff, the contractor shall, in addition to the above coverage, secure at its own expense the following coverage:

| | |
|---|---|
| e) Automotive Liability (Bodily Injury) | $100,000/$300,000 |
| f) Automotive Property Damage (to others) | $ 25,000 |

4. Not withstanding the information contained above, the Contractor shall indemnify and hold harmless the State of Delaware, the Department and the Divisions from contingent liability to others for damages because of bodily injury, including death, that may result from the Contractor's negligent performance under this Contract, and any other liability for damages for which the Contractor is required to indemnify the State, the Department and the Divisions under any provision of this Contract.

5. The policies required under Paragraph B3 must be written to include Comprehensive General Liability coverage, including Bodily Injury and Property damage insurance to protect against claims arising from the performance of the Contractor and the contractor's subcontractors under this Contract and Medical/Professional Liability coverage when applicable.

6. The Contractor shall provide a Certificate of Insurance as proof that the Contractor has the required insurance. The certificate shall identify the Department and the Divisions as the "Certificate Holder" and shall be valid for the contract's period of performance as detailed in Paragraph A 2.

7. The Contractor acknowledges and accepts full responsibility for securing and maintaining all licenses and permits, including the Delaware business license, as applicable and required by law, to engage in business and provide the goods and/or services to be acquired under the terms of this Contract. The Contractor acknowledges and is aware that Delaware law provides for significant penalties associated with the conduct of business without the appropriate license.

8. The Contractor agrees to comply with all State and Federal licensing standards and all other applicable standards as required to provide services under this Contract, to assure the quality of services provided under this Contract. The Contractor shall immediately notify the Department in writing of any change in the status of any accreditations, licenses or certifications in any jurisdiction in which they provide

services or conduct business. If this change in status regards the fact that its accreditation, licensure, or certification is suspended, revoked, or otherwise impaired in any jurisdiction, the Contractor understands that such action may be grounds for termination of the Contract.

a) If a contractor is under the regulation of any Department entity and has been assessed Civil Money Penalties (CMPs), or a court has entered a civil judgment against a Contractor or vendor in a case in which DHSS or its agencies was a party, the Contractor or vendor is excluded from other DHSS contractual opportunities or is at risk of contract termination in whole, or in part, until penalties are paid in full or the entity is participating in a corrective action plan approved by the Department.

A corrective action plan must be submitted in writing and must respond to findings of non-compliance with Federal, State, and Department requirements. Corrective action plans must include timeframes for correcting deficiencies and must be approved, in writing, by the Department.

The Contractor will be afforded a thirty (30) day period to cure non-compliance with Section 8(a). If, in the sole judgment of the Department, the Contractor has not made satisfactory progress in curing the infraction(s) within the aforementioned thirty (30) days, then the Department may immediately terminate any and/or all active contracts.

9. Contractor agrees to comply with all the terms, requirements and provisions of the Civil Rights Act of 1964, the Rehabilitation Act of 1973 and any other federal, state, local or any other anti discriminatory act, law, statute, regulation or policy along with all amendments and revision of these laws, in the performance of this Contract and will not discriminate against any applicant or employee or service recipient because of race, creed, religion, age, sex, color, national or ethnic origin, disability or any other unlawful discriminatory basis or criteria.

10. The Contractor agrees to provide to the Divisions Contract Manager, on an annual basis, if requested, information regarding its client population served under this Contract by race, color, national origin or disability.

11. This Contract may be terminated in whole or part:

a) by the Department upon five (5) calendar days written notice for cause or documented unsatisfactory performance,

b) by the Department upon fifteen (15) calendar days written notice of the loss of funding or reduction of funding for the stated Contractor services as described in Appendix B,

c) by either party without cause upon thirty (30) calendar days written notice to the other Party, unless a longer period is specified in Appendix A.

In the event of termination, all finished or unfinished documents, data, studies, surveys, drawings, models, maps, photographs, and reports or other material prepared by Contractor under this contract shall, at the option of the Department, become the property of the Department.

In the event of termination, the Contractor, upon receiving the termination notice, shall immediately cease work and refrain from purchasing contract related items unless otherwise instructed by the Department.

The Contractor shall be entitled to receive reasonable compensation as determined by the Department in its sole discretion for any satisfactory work completed on such documents and other materials that are usable to the Department. Whether such work is satisfactory and usable is determined by the Department in its sole discretion.

Should the Contractor cease conducting business, become insolvent, make a general assignment for the benefit of creditors, suffer or permit the appointment of a receiver for its business or assets, or shall avail itself of, or become subject to any proceeding under the Federal Bankruptcy Act or any other statute of any state relating to insolvency or protection of the rights of creditors, then at the option of the Department, this Contract shall terminate and be of no further force and effect. Contractor shall notify the Department immediately of such events.

12. Any notice required or permitted under this Contract shall be effective upon receipt and may be hand delivered with receipt requested or by registered or certified mail with return receipt requested to the addresses listed below. Either Party may change its address for notices and official formal correspondence upon five (5) days written notice to the other.

To the Division at:
Division of Medicaid & Medical Assistance

Attn: Transportation Program Manager

P.O. Box 906

New Castle, Delaware 19720

To the Contractor at:

Logisticare Solutions, LLC

1275 Peachtree St, NE, 6th. Floor

Atlanta, Georgia 30309

13. In the event of amendments to current Federal or State laws which nullify any term(s) or provision(s) of this Contract, the remainder of the Contract will remain unaffected.

14. This Contract shall not be altered, changed, modified or amended except by written consent of all Parties to the Contract.

15. The Contractor shall not enter into any subcontract for any portion of the services covered by this Contract without obtaining prior written approval of the Department. Any such subcontract shall be subject to all the conditions and provisions of this Contract. The approval requirements of this paragraph do not extend to the purchase of articles, supplies, equipment, rentals, leases and other day-to-day operational expenses in support of staff or facilities providing the services covered by this Contract. Notwithstanding the foregoing, contracts with Non-emergency medical transportation providers do not require prior consent of the Department.

16. This entire Contract between the Contractor and the Department is composed of these several pages and the attached:

Appendix A - Divisional Requirements

Appendix B - Services Description

Appendix C - Contract Budget

Appendix D – Client Confidentiality, PM # 5

Appendix E - Public Health Title 42, 455 Subpart B

Appendix F – Public Health Title 42, 1001 Subpart D

Appendix G – State Medicaid Directors Letter #08-003

Appendix H – State Medicaid Directors Letter #09-001

Appendix I - Disclosure of Ownership and Control Interest Statement

17. This Contract shall be interpreted and any disputes resolved according to the Laws of the State of Delaware. Except as may be otherwise provided in this contract, all claims, counterclaims, disputes and other matters in question between the Department and Contractor arising out of or relating to this Contract or the breach thereof will be decided by arbitration if the parties hereto mutually agree, or in a court of competent jurisdiction within the State of Delaware.

18. In the event Contractor is successful in an action under the antitrust laws of the United States and/or the State of Delaware against a vendor, supplier, subcontractor, or other party who provides particular goods or services to the Contractor that impact the budget for this Contract, Contractor agrees to reimburse the State of Delaware, Department of Health and Social Services for the pro-rata portion of the damages awarded that are attributable to the goods or services used by the Contractor to fulfill the requirements of this Contract. In the event Contractor refuses or neglects after reasonable written notice by the Department to bring such antitrust action, Contractor shall be deemed to have assigned such action to the Department.

Contractor covenants that it presently has no interest and shall not acquire any interests, direct or indirect, that would conflict in any manner or degree with the performance of this Contract. Contractor further covenants that in the performance of this contract, it shall not employ any person having such interest.

Contractor covenants that it has not employed or retained any company or person who is working primarily for the Contractor, to solicit or secure this agreement, by improperly influencing the Department or any of its employees in any professional procurement process; and, the Contractor has not paid or agreed to pay any person, company, corporation, individual or firm, other than a bona fide employee working primarily for the Contractor, any fee, commission, percentage, gift or any other consideration contingent upon or resulting from the award or making of this agreement. For the violation of this provision, the Department shall have the right to terminate the agreement without liability and, at its discretion, to deduct from the contract price, or otherwise recover, the full amount of such fee, commission, percentage, gift or consideration.

The Department shall have the unrestricted authority to publish, disclose, distribute and otherwise use, in whole or in part, any reports, data, or other materials prepared under this Contract. Contractor shall have no right to copyright any material produced in whole or in part under this Contract. Upon the request of the Department, the Contractor shall execute additional documents as are required to assure the transfer of such copyrights to the Department.

If the use of any services or deliverables is prohibited by court action based on a U.S. patent or copyright infringement claim, Contractor shall, at its own expense, buy for the Department the right to continue using the services or deliverables or modify or replace the product with no material loss in use, at the option of the Department.

Contractor agrees that no information obtained pursuant to this Contract may be released in any form except in compliance with applicable laws and policies on the confidentiality of information and except as necessary for the proper discharge of the Contractor's obligations under this Contract.

Waiver of any default shall not be deemed to be a waiver of any subsequent default. Waiver or breach of any provision of this Contract shall not be deemed to be a waiver of any other or subsequent breach and shall not be construed to be a modification of the terms of the Contract unless stated to be such in writing, signed by authorized representatives of all parties and attached to the original Contract.

24. If the amount of this contract listed in Paragraph C2 is over $25,000, the Contractor, by their signature in Section E, is representing that the Firm and/or its Principals, along with its subcontractors and assignees under this agreement, are not currently subject to either suspension or debarment from Procurement and Non-Procurement activities by the Federal Government.

C) Financial Requirements

1. The rights and obligations of each Party to this Contract are not effective and no Party is bound by the terms of this contract unless, and until, a validly executed Purchase Order is approved by the Secretary of Finance and received by Contractor,

*if required by the State of Delaware Budget and Accounting Manual,* and all policies and procedures of the Department of Finance have been met. The obligations of the Department under this Contract are expressly limited to the amount of any approved Purchase Order. The State will not be liable for expenditures made or services delivered prior to Contractor's receipt of the Purchase Order.

2. Total payments under this Contract shall not exceed $24,100,000 in accordance with the budget presented in Appendix C. Payment will be made upon receipt of an itemized invoice from the Contractor in accordance with the payment schedule, if any. The contractor or vendor must accept full payment by procurement (credit) card and or conventional check and/or other electronic means at the State's option, without imposing any additional fees, costs or conditions. Contractor is responsible for costs incurred in excess of the total cost of this Contract and the Department is not responsible for such costs.

The Department has budgeted $24.1 Million for total per member per month payments under this Contract in accordance with the budget presented in Appendix C, however, actual total payments may vary based upon monthly Medicaid eligible member counts. Monthly payments will be processed by the Department and Divisions Medicaid Fiscal Agent through the Medicaid Management Information System (MMIS) in accordance with the payment schedule, if any. The contractor or vendor must accept full payment by procurement (credit) card and or conventional check and/or other electronic means at the State's option, without imposing any additional fees, costs or conditions.

3. The Contractor is solely responsible for the payment of all amounts due to all subcontractors and suppliers of goods, materials or services which may have been acquired by or provided to the Contractor in the performance of this contract. The Department is not responsible for the payment of such subcontractors or suppliers.

4. The Contractor shall not assign the Contract or any portion thereof without prior written approval of the Department and subject to such conditions and revisions as the Department may deem necessary. No such approval by the Department of any assignment shall be deemed to provide for the incurrence of any obligations of the Department in addition to the total agreed upon price of the Contract.

5. Contractor shall maintain books, records, documents and other evidence directly pertinent to performance under this Contract in accordance with generally accepted accounting principles and practices. Contractor shall also maintain the financial

information and data used by Contractor in the preparation of support of its bid or proposal. Contractor shall retain this information for a period of five (5) years from the date services were rendered by the Contractor. Records involving matters in litigation shall be retained for one (1) year following the termination of such litigation. The Department shall have access to such books, records, documents, and other evidence for the purpose of inspection, auditing, and copying during normal business hours of the Contractor after giving reasonable notice. Contractor will provide facilities for such access and inspection.

6. The Contractor agrees that any submission by or on behalf of the Contractor of any claim for payment by the Department shall constitute certification by the Contractor that the services or items for which payment is claimed were actually rendered by the Contractor or its agents, and that all information submitted in support of the claims is true, accurate, and complete.

7 The cost of any Contract audit disallowances resulting from the examination of the Contractor's financial records will be borne by the Contractor. Reimbursement to the Department for disallowances shall be drawn from the Contractor's own resources and not charged to Contract costs or cost pools indirectly charging Contract costs.

8. When the Department desires any addition or deletion to the deliverables or a change in the services to be provided under this Contract, it shall so notify the Contractor. The Department will develop a Contract Amendment authorizing said change. The Amendment shall state whether the change shall cause an alteration in the price or time required by the Contractor for any aspect of its performance under the Contract. Pricing of changes shall be consistent with those prices or costs established within this Contract. Such amendment shall not be effective until executed by all Parties pursuant to Paragraph B 14.

D) Miscellaneous Requirements

1. *If applicable*, the Contractor agrees to adhere to the requirements of DHSS Policy Memorandum # 46, (PM # 46, effective 3/11/05), and Divisional procedures regarding the reporting and investigation of suspected abuse, neglect, mistreatment, misappropriation of property and significant injury of residents/clients receiving services, including providing testimony at any administrative proceedings arising from such investigations. The policy and procedures are included as Appendix _____ to this Contract. It is understood that adherence to this policy includes the development of appropriate procedures to implement the policy and ensuring staff receive appropriate training on the policy requirements. The Contractor's procedures must include the position(s) responsible for the PM46 process in the provider agency. Documentation of staff training on PM46 must be maintained by the Contractor.

2. The Contractor, including its parent company and its subsidiaries, and any subcontractor, including its parent company and subsidiaries, agree to comply with the provisions of 29 Del. Code, Chapter 58: "Laws Regulating the Conduct of Officers and Employees of the State," and in particular with Section 5805 (d): "Post Employment Restrictions."

3. *When required by Law*, Contractor shall conduct child abuse and adult abuse registry checks and obtain service letters in accordance with 19 Del. Code Section 708; and 11 Del. Code, Sections 8563 and 8564. Contractor shall not employ individuals with adverse registry findings in the performance of this contract.

4. *If applicable*, the Contractor agrees to adhere to the requirements of DHSS Policy Memorandum # 40 (PM #40), effective 3/10/2008), and Divisional procedures regarding conducting criminal background checks and handling adverse findings of the criminal background checks. This policy and procedure are included as Appendix _____ to this Contract. It is understood that adherence to this policy includes the development of appropriate procedures to implement the policy and ensuring staff receive appropriate training on the policy requirements. The Contractor's procedures must include the title of the position(s) responsible for the PM40 process in the contractor's agency.

5. *If applicable,* the Contractor agrees to adhere to the requirements of DHSS Policy Memorandum # 36 (PM #36, effective 9/24/2008), and Divisional procedures regarding minimal requirements of contractors who are engaging in a contractual agreement to develop community based residential arrangements for those individuals served by Divisions within DHSS. This policy and procedure are included as Appendix ____ to this Contract. It is understood that adherence to this policy includes individuals/entities that enter into a contractual arrangement (*contractors*) with the DHSS/Divisions to develop a community based residential home(s) and apartment(s). Contractors shall be responsible for their subcontractors adherence with this policy and related protocol(s) established by the applicable Divisions.

6. All Department campuses are tobacco-free. Contractors, their employees and sub-contractors are prohibited from using any tobacco products while on Department property. This prohibition extends to personal vehicles parked in Department parking lots.

E) Authorized Signatures:

For the Contractor:

Signature

Name

Chief Administrative Officer
Title

3/15/2011
Date

For the Department:

...ata M. Langraf
Secretary

3/18/11
Date

For the Divisions:

Rosanne Mahaney
Director – Division of
Medicaid & Medical
Assistance

3/16/11
Date

Gary Heckert
Director – Division of
Management Services

3/18/11
Date

**APPENDIX A**

## DIVISIONAL REQUIREMENTS

1. The Contractor agrees to meet or exceed all minimum service standards as indicated in the scope of service and all other requirements and specifications contained in Request for Proposal HSS-10-091. Furthermore, if at any given time, the Contractor cannot meet all requirements contained in Request for Proposal HSS-10-091. The Division of Medicaid and Medical Assistance (DMMA) (The Division) has the authority to withhold liquidated damages in the amount specified in Addendum #3, Appendix A-2 of the Request for Proposal HSS-10-091 for each day that it fails to meet specific Performance Measurements or Standards.

2. The Contractor agrees that the project will be carried out in accordance with the policies and procedures established by the Department, the Division and the terms and conditions of this contract, Request for Proposal HSS-10-091 and Contractor's Business and Technical proposal.

3. The Contractor must maintain documentation, as identified in the RFP to support all payments submitted to and paid by the Division.

4. The Contractor's fiscal records and accounts, including those involving other programs that may be substantially related to this contract, shall be subject to audit by duly authorized Federal and State officials.

5. The Contractor agrees to submit monthly, quarterly, annual and special reports described in Request for Proposal HSS-10-091. The Contractor shall pay or the Divisions will withhold liquidated damages in the amount specified in Addendum #3, Appendix A-2 of the Request for Proposal HSS-10-091for each day it fails to submit the reports by the date required defined in the contract, or otherwise agreed to by the Parties.

6. The Contractor agrees to cooperate and assist in efforts undertaken by the Divisions, the U.S. Department of Health and Human Services, or any other agency or organization duly authorized by any of the preceding to evaluate the effectiveness, feasibility and cost of the program.

7. The Contractor agrees to fully comply with the Department of Health and Social Services, Policy Memorandum Number 5, Client Confidentiality (see Appendix D). The Contractor agrees that any personal information that is electronically communicated will be secured. The Contractor further agrees that communicating Social Security Numbers, using any media is prohibited.

8. The Contractor will provide the program coordinator (i.e. name as provided on the Certificate of Insurance, in the Certificate Holder location) with copy of insurance's held and will provide copy of same when there is any change in status to policy.

9. No part of any funds under this contract shall be used to pay the salary or expenses of any contractor or agent acting for the contractor, to engage in any activity (lobbying) designed to influence legislation or appropriations pending before the State Legislature and/or Congress.

10. The Contractor agrees to fully comply with the Social Security Administration, Public Health Title 42 Part 455 Subpart B Program Integrity: Medicaid, Disclosure of Information by Providers and Fiscal Agents (see Appendix E, G and H). To fully comply with this requirement the Contractor agrees to conduct exclusion searches using the HHS, Office of Inspector General's List of Excluded Individuals/Entities (LEIE), the Medicare Exclusion Database and the Excluded Parties List System (EPLS).
http://exclusions.oig.hhs.gov www.epls.gov

11. The Contractor agrees to fully comply with the Social Security Administration, Public Health Title 42 Part 1001 Subpart D Program Integrity: Medicare and State Health Care Programs, Waivers and Effect of Exclusion (see Appendix F, G and H). To fully comply with this requirement the Contractor agrees to conduct exclusion searches using the HHS, Office of Inspector General's List of Excluded Individuals/Entities (LEIE), the Medicare Exclusion Database and the Excluded Parties List System (EPLS).
http://exclusions.oig.hhs.gov www.epls.gov

**APPENDIX B**

## SERVICE DESCRIPTION

The Medicaid non-emergency transportation (NET) program is a result of a Request for Proposal (RFP) No. HSS-10-091dated September 16, 2010 and was developed as part of a cost containment measure and to increase efficiency. NET services are defined in the RFP as necessary non-emergency transportation services provided to Delaware Medicaid Assistance Program (DMAP) clients who have no other means of transportation. Necessary transportation is defined as the least expensive mode of transportation available that is appropriate to the medical and or functional needs of the client. NET service ensures reasonable access for DMAP clients to a medical service for the purpose of receiving treatment and/or medical evaluation.

The Division of Medicaid and Medical Assistance (DMMA) contracts with one Contractor to be responsible for the administration and provision of NET transportation in each of the three counties in Delaware to include wheelchair van, non-emergency ambulance, public transportation and car/station wagon, minivan services and mileage reimbursement. Non-emergency ambulance transportation is restricted to those clients who require transport by stretcher. The actual transportation services under the Contract and RFP is provided through subcontracts between the Contractor and transportation providers. The Contractor verifies client eligibility, coordinates trips, reimburses NET service providers and employs accountability measures to ensure effective utilization of services and expenditures. This administrative approach allows for the extensive coordination of trips and appropriate use of DMAP services and expenditures.

APPENDIX C

# DEPARTMENT OF HEALTH AND SOCIAL SERVICES
# DIVISION OF MEDICAID AND MEDICAL ASSISTANCE
# NON-EMERGENCY TRANSPORTATION PROGRAM BUDGET

| CONTRACTOR | CONTRACT PERIOD | BUDGET |
|---|---|---|
| LOGISTICARE SOLUTIONS | APRIL 1, 2011 THROUGH MARCH 31, 2012 | $11,700,000 |
| LOGISTICARE SOLUTIONS | APRIL 1, 2012 THROUGH MARCH 31, 2013 | $12,400,000 |
| TOTAL TWO (2) YEAR BUDGET | | $24,100,000 |

**APPENDIX D**

# CLIENT CONFIDENTIALITY

**DELAWARE HEALTH AND SOCIAL SERVICES**

**POLICY MEMORANDUM NUMBER 5**

November 8, 2000

**SUBJECT:** CLIENT CONFIDENTIALITY

## I. POLICY STATEMENT – PHILOSOPHY

It is the policy of Delaware Health and Social Services to recognize that when a client provides information about himself or herself to the Department, that individual is placing trust in each and every Department employee or agent thereof. Furthermore, this Client Confidentiality Policy is not only a legal requirement but is also written evidence of a commitment or promise to our clients that we will respect their privacy. This policy assures that a Department employee or agent will only have access to individual client information that he or she needs to know. It assures that we will not tolerate any unnecessary release of confidential information by anyone in the Department. It assures that we will educate our employees, agents, clients, and the public concerning the client's right to confidentiality, the client's right to restrict or limit dissemination of confidential information, and the client's right to know the Department's policies and procedures regarding access, disclosure and explanation or correction.

## II. PURPOSE

Confidentiality is a highly complex subject. The purpose of this policy is to:
1. Maintain the Department's ethical, professional, and legal obligation to protect clients from undue intrusion of privacy;
2. Safeguard recorded and unrecorded knowledge or information about individuals, while permitting the exchange of information required to provide and monitor quality services;
3. Permit the appropriate use and disclosure of essential oral and written information when such sharing is professionally judged to be in the best interest of the clients in its care, when there is a legitimate need to know, and with appropriate client consent;
4. Ensure that the Department's handling of confidential information is consistent with applicable laws, rules, and recommended professional practice. These applicable laws, regulations, and guidelines can be found in the Reference Section; and
5. Set forth guidelines and procedures that complement federal and state mandates.

## I. SCOPE

This policy applies to all employees within the Department and their facilities, bureaus, offices and other administrative entities. This policy also applies to Department agents including students, volunteers, contractors, foster parents, providers, researchers, or any others such as auditors, who may come in contact with client information.
If circumstances occur for which there is any doubt as to our authority to release confidential information and for which this policy does not offer guidance, the Department will obtain the advice of legal counsel prior to releasing the information.

## II. DEFINITIONS

A. Agency: Delaware Health and Social Services or any subdivision within the Department.
B. Client: any individual named in any record maintained by the Department except employee-related records.
C. Confidential: the entrusting of information to another individual with the understanding that the information will not be disclosed.
D. Confidential Information: any item, collection or grouping of information which contains the name of an individual or any identifying number, symbol, other identifying characteristics, or any unique grouping of information which makes the individual as recognizable as if a name had been affixed.
E. Department: refers to Delaware Health and Social Services as an entity, including all Divisions and the Office of the Secretary.
F. Department Agent: anyone acting on behalf of the Department.
G. Disclosure: to communicate, transmit or otherwise convey any data to any individual or organization in any form, either written, verbal or otherwise. This includes the affirmative verification of another person's communication of personally identifying information.
H. Guardian: any individual who has been appointed as a guardian of the person by a court of competent jurisdiction, and shall include an individual or agency which has been awarded legal custody by a court of competent jurisdiction.
I. Individual: a natural person, living or dead.
J. Informed Consent: agreement to an action after understanding what is involved.
K. Minor: any individual under the age of 18 years.
L. Need to Know Basis: when it is essential to have information regarding a client in order to provide necessary service linkage and treatment planning. Information obtained for one purpose may not be used for any other unrelated purpose.
M. Parent: an adoptive or biological parent who has not lost parental rights (i.e., parental rights have not been terminated).
N. Personally Identifiable Information: information that includes:

1. name; address; or personal identifiers, such as the social security number, certificate number, driver's license number, or date of birth; or

2. a description or composite of personal characteristics, a record number or other information that would make it possible to identify the client or other family member with reasonable accuracy, either directly or by reference to other publicly available information.

A. Record: any item, collection, grouping, or information that is maintained by a Department agency and contains personally identifiable information, to also include electronic records.

B. System of Records: a group of any records under the control of any Department agency from which information is retrieved by an identifying name, number, or symbol, to also include electronic records.

## I. PROCEDURES

### A. Obtaining of Information by the Department

1. Accuracy: The Department shall make reasonable efforts to assure accuracy, completeness, relevancy and timely entry for all records. The Department shall maintain in its records only such information as is necessary to accomplish the agency's purpose. All record entries shall be pertinent to the nature of the service and the needs of the client. Divisions shall establish procedures to insure accuracy, completeness, relevancy and timeliness of records.

2. Primary Source: Individuals or their legally authorized representatives shall be the primary source of information about themselves and their families. Within the guidelines of this policy and Division procedures, clients shall be invited to be involved in meetings where they are the main subject.

3. Privacy Protection: Client interviews shall be conducted in a manner which provides privacy. Clients shall not be filmed, taped, photographed or observed without their knowledge and written consent, except where permitted by statute or the purpose of civil and/or criminal law enforcement.

4. Each client, patient, and/or resident shall be treated with respect and provided privacy when receiving health or social services. Case discussion, consultation, examination and treatment shall be confidential and conducted discreetly. Persons not directly involved in the service delivery shall not be permitted to be present during discussion, consultation, examination or treatment unless the client has given prior informed consent for such person(s) to be present. Indiscriminate disclosure of information is unethical.

5. Written Consent: When requesting information from sources outside of the Department, written informed consent must be secured from the individual adult to whom the records refer, a minor's parent/guardian, or the legally authorized representative for the individual to whom the

records refer except as provided by DHSS policy or state law.
6. Advising Informants About Policy on Confidentiality: Individuals from whom confidential information is elicited shall be informed of the Department's authority, policy and purposes for such collection, and particularly the individual's rights as contained in this policy in a language that is understood by the individual. (Attachment A: Confidentiality Notice to Clients)

**A. Safeguarding of Information by the Department**

1. Records Ownership: Records are the property of the Department.
2. Record Review: Each Division will establish procedures for safeguarding records.
3. Staff Access to Confidential Information: Department employees and agents shall only access confidential information that they have a legitimate need to know.
4. Confidentiality Training and Agreement: since any Department employee or agent may come into contact with confidential information, all such individuals will be made aware of this policy.
5. Disclosure Accounting: Each Division shall maintain a system of documentation and accountability for any disclosure of confidential information.
6. Storage: Written and electronically recorded confidential information shall be stored in a systematic and secure manner, to insure the security and confidentiality of records and to protect against potential threats to their security or integrity.
7. Retention and Disposal of Records: All staff shall follow Delaware Code and Department policy regarding record retention and disposal of records.
8. Record Removal: Records or parts thereof shall not be removed from Department offices unless prior authorization has been obtained.
9. Exclusions to Department Ownership of Records: Client information maintained by the following programs and/or services is not considered to be Department information and shall not be shared either within or outside the Department without prior written consent by the client: HIV/AIDS, ombudsman, alcohol and substance abuse, and sexually-transmitted diseases.

**A. Releasing of Information by the Department**

1. Circumstances When Disclosure Is Never Permitted: Unless requested under a statute, court order, or for criminal or civil law enforcement, the following information may not be disclosed to anyone.

a. Other's Rights: Information that would violate the confidentiality rights of others, including other family members, without their specific written consent. If it is not possible to remove confidential

information that refers to others, and no written consent has been obtained from the affected person(s), a summary which excludes the confidential information shall be provided.

b. Source's Identity: Reports that would reveal the identity of a source who gave information under promise that their identity would be kept confidential.

c. Sealed Records: Information concerning termination of parental rights, adoptions and some custody matters are sealed. Individuals wishing to gain such information must petition the Family Court.

2. Disclosure as Permitted with Informed Written Consent: The Department shall not disclose or knowingly permit the disclosure of any information, by any means of communication, to any person or other organization except with written informed consent or pursuant to statute or for law enforcement purposes.

a. Consent Form: A consent-for-release-of-confidentialinformation form, at a minimum, must provide:

(1) the identity of the person about whom the information is being released;
(2) the identity of the program, unit or facility releasing the information;
(3) the type of information being requested and the purpose for its use;
(4) the identity and title of the person requesting the information;
(5) the time period for which the permission remains in effect;
(6) a revocation-of-consent statement;
(7) the signature of the person requesting the information and/or his/her parent or guardian, if appropriate, and the date of request; and
(8) the signature of the person about whom the information pertains and/or their parent/legal guardian, or their legally authorized representative, and date signed.

a. Voluntary Consent: The consent must be voluntarily given and the client can revoke consent at any time. Individual(s) shall be informed if their decision concerning the release of information will result in denial, change, or termination of services.

b. Disclosure Not Required: A signed consent for release of information does not require the Department to release information. In the absence of legal counsel, individuals may inadvertently compromise their own due process or other legal protection. Therefore, Department employees and agents shall carefully consider the best interests of the client before complying with a request for information.

c. Verification of Identity: In the event that the identity of

the requesting person cannot be verified, Department employees shall obtain appropriate documentation.

d. Release Limited to Primary Disclosure: Release of information by the Department shall be limited to that which was specifically generated by the Department or its agents.

e. Minors: When the individual to whom the record refers is a minor (less than 18 years old), a parent or guardian must sign the consent for release. The exceptions are:

(1) If the parent is unable or unwilling, a legal custodian may act on the child's behalf, in his/her best interests and consistent with applicable law.

(2) If the program under which the minor is receiving services does not require parental consent in order to provide services, parental consent cannot be requested. In such cases, the minor must always sign the consent for release of information.

(3) Information about program attendance or the treatment of a minor age 12 years or older for pregnancy, sexually transmitted diseases, or alcohol abuse may not be released without the written consent of the minor. Parental consent cannot be requested.

(4) If the person is an emancipated minor, as defined by state law, parental consent cannot be requested.

a. Research: Researchers shall follow DHSS policy memoranda and guidelines concerning the protection of human subjects.

b. Inquiries from Public Officials, the Press or the General Public: Media, press, general public, legislative or other public officials' requests for information shall be directed according to specific procedure outlined by the Department or Division.

c. Notice Prohibiting Redisclosure: Whenever a written disclosure of confidential information is made, the disclosure shall be accompanied by a written statement substantially as follows: "This information has been disclosed to you from records whose confidentiality is protected by federal and state laws. You are prohibited from making any further disclosure of this information."

(1) Transmission of Electronic Facsimiles:

When a facsimile of confidential information is transmitted electronically, it shall be accompanied by a cover sheet with the agency's name, address and telephone number and a confidentiality notice reading as follows:

This facsimile (this page and accompanying page[s]) is intended only for the use of the individual or entity to whom it is addressed and may contain information that is privileged, confidential and exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or the

employee or agent responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution, or copying of this communication, or the taking of any action in reliance on the contents of this information, may be strictly prohibited. If you have received this facsimile in error, please notify us immediately by telephone and return the original to us at the above address. Thank you.

1. Circumstances when Consent to Release is not Required: Consent to release information is not required in the following circumstances:

a. Medical Emergencies and Public Health or Safety: In medical emergencies or when necessary to protect or warn others of imminent threats to their safety, essential pertinent information shall be revealed.

b. State and Federal Laws: State law requires every individual to report suspected abuse to applicable agency(ies) in accordance with state and federal laws.

c. Involuntary Receipt of Protective Services: State law permits delivery of adult protective services to a person who lacks the capacity to consent.

d. Federal Laws: Federal law requires licensed nursing facilities to report suspected (impaired adult) abuse or neglect to the Division of Long-Term Care Residents Protection, as well as to the Division of Services for Aging and Adults with Physical Disabilities.

e. Exchange of Information Among Department Service Providers: Responsible exchange of information among Department employees consistent with the spirit of this policy may occur without written consent when:

(1) providing Department services and there is a need to know; or

(2) protecting the public health or safety.

a. Audit or Program Evaluation: Administrative audit or program evaluation does not require signed consent when:

(1) clients are identified only for the program being evaluated;

(2) no personally identifiable information is disclosed in any reports; and

(3) no records are copied or removed unless personally identifiable information is deleted or blocked out so as to be undecipherable.

a. Research: A signed consent is not required to provide information for research purposes if:

(1) approval is obtained following appropriate state and DHSS policies such as a Human Subjects Review Board clearance; or

(2) no records are copied or removed unless

personally identifiable information is deleted or blocked out so as to be undecipherable.

a. CASA: The order that the court issues when appointing a Court Appointed Special Advocate (CASA or guardian ad litem) specifies permission to inspect and/or copy any records relating to the child and his or her family/guardian. However, each order shall be reviewed to determine the CASA authority.

b. Court Order: Information may be released to comply with a court order, provided that reasonable effort is made to notify the client of the order in advance of compliance; if notification of the client is not in violation of the court order and is in the best interest of the client or the Department.

c. Disciplinary Proceedings: When necessary, client records may be used to substantiate less than standard job performance or misconduct of Department employees. All identifiable information shall be removed.

d. Other Exceptions: The law permits some other fairly technical exceptions. For example, after a period of years, certain vital statistics records may become available for public inspection. In cases where uncertainty arises as to whether informed written consent is required, supervisory advice, advice of legal counsel, or a specific court order shall be obtained.

e. Notification of Client: If information is released under the procedures applying to CASA, court orders, or other technical exceptions, pertinent details of the reasons for the release shall be documented and written notification of this release shall be sent to the last known address of the person to whom the record refers.

4. Other Considerations

a. HIV/AIDS (Human Immunodeficiency Virus/Acquired Immunodeficiency Virus); No person may disclose or be compelled to disclose the identity of any person upon whom an HIV-related test is performed, or the results of such a test in a manner which permits identification of the subject of the test, except to the following person(s):

(1) the subject of the test or the subject's legal guardian;

(2) any person with a written release (must be signed by the subject or guardian, which is dated and specifies to whom disclosure is authorized and the time period during which the release is effective);

(3) Department employees or agents who provide patient care or handle specimens of blood, body fluids, or other tissues, and have a medical need to know such information to provide health care;

(4) Health care workers providing medical care when the test result is necessary for emergency care or

treatment;
(5) the Division of Public Health when part of an official report as may be required by regulation;
(6) a health facility or provider which procures, processes, distributes or uses blood, human body parts, or semen for the purposes of transplant or donation;
(7) health facility staff, committee accreditation or oversight review organizations conducting program evaluation;
(8) pursuant to laws relating to the investigation of child/impaired adult abuse;
(9) persons allowed access to such information by court order, given certain restrictions; and
(10) pursuant to laws relating to sexually transmitted diseases and their control.

a. Sexually Transmitted Diseases (STDs): All information and records held by the Division of Public Health relating to known or suspected cases of STDs, including infection with the virus causing AIDS shall be strictly confidential. Such information shall not be released or made public upon subpoena or otherwise, except the following:

(1) Release is made of medical or epidemiological information for statistical purposes so that no person can be identified.
(2) Release is made of medical or epidemiological information with the consent of all person(s) identified in the information releases.
(3) Release is made of medical or epidemiological information to medical personnel, appropriate state agencies or state courts to the extent required to enforce the provision of 16 Delaware Code and related rules and regulations concerning the control and treatment of STDs, or as related to child abuse investigations.
(4) Release is made of medical or epidemiological information to medical personnel in a medical emergency to the extent necessary to protect the health or life of the named party; or
(5) Release is made during the course of civil or criminal litigation to a person allowed access to said records by a court order which is issued in compliance with the following provisions:

a. No court of this State shall issue such order unless the court finds that the person seeking the records and information has demonstrated a compelling need for such records which cannot be accommodated by other means. In assessing

compelling need, the court shall weigh the need for disclosure against the privacy interest of the subject and the public interest which may be disserved by the disclosure which deters future testing and treatment or which may lead to discrimination.

b. Pleadings pertaining to disclosure of such records shall substitute a pseudonym for the true name of the subject of the records. The disclosure to the parties of the subject's true name shall be communicated confidentially, in documents not filed with the court.

c. Before granting any such order, the court shall provide the subject whose records are in question with notice and a reasonable opportunity to participate in the proceedings if he or she is not already a party.

d. Court proceedings as to disclosure of such records shall be conducted in camera unless the subject agrees that a hearing is necessary to the public interest and the proper administration of justice.

e. Upon issuance of an order to disclose such records, the court shall impose appropriate safeguards against unauthorized disclosure, which shall specify the persons who have access to the information, the purposes for which information shall be used, and appropriate prohibitions on future disclosures.

(6) No state or local health department officer or employee shall be examined in a civil, criminal, special or other proceeding as to the existence or contents of pertinent records for a person examined or treated for an STD or HIV infection by the Division of Public Health, or of the existence or contents of such reports received from a private health care professional or private health facility, without the consent of the person examined and treated for such diseases, except where the information in such records is disclosed pursuant to the law.

a. Alcohol and Other Drug Information: All information maintained by alcohol and drug treatment programs is protected by federal laws. Such information may not be disclosed except under certain conditions as specified in federal law.

b. Minors: Information related to the medical examination, consultation, or treatment of a minor for sexually transmitted diseases and pregnancy-related conditions is considered confidential and shall not be released. Three exceptions apply:

(1) reporting required by law;

(2) child abuse investigation; and
(3) mental health records.

**D. Providing Clients Access to Their Records**

1. Disclosure to Clients:

a. Right to Know: Individuals have a right to find out what records are maintained about them, how they will be used, and how they will be shared with others. Individuals have a right to review their records, including disclosure accounting specified in this policy. The only exception to this is that records developed in the investigation of waste, abuse, or fraud are not subject to review.

b. Procedures for Accessing Records: An individual or their legally authorized representative (or, in the case of a minor, a parent or guardian) must submit a written request. The requester's identity must be verified and the records shall be reviewed in the presence of a Department professional. The requester may bring a support person or representative to the review and may take notes or have copies of these records made. A fee may not be charged to search for or retrieve Department records for this purpose. A fee may be charged for copies.

c. Record Review: When an individual reviews Department records, a Department professional shall carry out the review in a manner that protects the confidentiality of other individuals who may be discussed in the record(s). The professional may also help interpret and explain the record(s), answer questions, and monitor the review.

d. Assistance with an Interpreter: If the individual is deaf or blind, has no written language, or speaks in a language other than English, agency personnel may provide a qualified interpreter in the client's native language or in the mode of communication usually used (e.g., sign language, Braille, or oral communication).

e. Disputed Information: When an individual disagrees with information in their record, they may provide a written statement to be included as a permanent part of their record. If the information has been released, the statement must be forwarded.

f. Deleted Information: If information has been deleted from a file and the file subsequently shared with a client, the client shall be informed that deletions have been made and their general nature, so as not to mislead as to completeness. The reasons for such actions shall be documented in the record.

2. When Disclosure to Client is not Permitted: The following information may not be disclosed, unless required by a subpoena or a valid court order.

a. Protected Information: Disclosure is not permitted when such disclosure would violate the confidentiality rights of others; when disclosure would reveal the identity of a source of information protected by confidentiality; or when disclosure involves records

sealed by the Court, such as termination of parental rights, adoptions and some custody matters.
b. Disclosure Could Result in Harm to Client: If direct access to certain sensitive information is perceived to be potentially harmful, supervisory guidance shall be sought to determine an appropriate course of action. Information which could result in harm shall not be voluntarily released. The basis for any decision to refuse access to information shall be documented. In such cases, the person shall be advised that such information may be disclosed to a qualified professional chosen by him or her if requested in writing.
c. Information Relevant to Anticipated Civil Action or Law Enforcement: Information compiled in reasonable anticipation of a civil action or proceeding or for enforcement of criminal laws shall not be released except as directed by the Attorney General's office.

## I. NONCOMPLIANCE

Failure to comply with any of the provisions of this policy and its procedures in any form could result in specific civil, criminal, and/or Department penalties.

## II. IMPLEMENTATION

A. Any part of this policy which is found to be in conflict with federal or state laws shall be null and void; all other parts shall remain operative.
B. The Division of Management Services (Human Resources) shall be responsible for maintaining this policy and its revisions.
C. The Division of Management Services (Human Resources) shall be responsible for developing training guidelines for the Divisions.
D. This policy will become effective upon issuance.

*[Signed]* 11/08/00

Gregg C. Sylvester, M.D. Date
Secretary

## I. REFERENCES

**A. Federal Laws and Rules Governing Confidentiality**
Federal Privacy Act of 1974 (Public Law 93-579, 5 U.S.C. 552(a); 7 U.S.C. dd-2, 290 ee-3, 290 ff-3, 602, 603, 606, 607, 611, 1302, 1306(a), 1320b-7; Individuals with Disabilities Act (P.L. 102-119); P.L. Section 1902(a)(7) of the Social Security Act; Section 11(e)(8) of the Food Stamp Act of 1977.

**B. Federal Regulations and Policies Concerning Confidentiality**
7 CFR 272.1(c); 21 CFR 1316.21; 42 CFR Part 2, part 431 subpart F; 45 CFR 205.50, 303.21; 56 CFR 117; Rehabilitation Services Manual (U.S. Department of Education, Office of Special Education and Rehabilitation services Administration).

**C. Delaware Code, Regulations and Policies Concerning Confidentiality**
Section 972(b) of Title 10; Sections 707, 708, 726(b), 924, 925 and 1111 of Title 13; Section 4111 of Title 14; Sections 903, 905(b), 908, 1153(d)(e)(f), 3107 through 3112, 33121(f); 3122, 3123(b), 3126, 3127, 9113 of Title 16; Section 5161, Subchapter V (Mental Health Patients Bill of Rights) of Title 16; Chapters 7, 11 (Subchapter I), and 12 of Title 16; Section 3913 of Title 24; Sections 705(a), 4707(e), 4709, 5806(f)(g), 9001(b), 9003(6)(16) of Title 29; Sections 381 Article III(b)(c), 5203 Article VII(a) of Title 31; Delaware Uniform Rules of Evidence, Rule 503(a)(b)(c); Delaware Merit System Rules; DHSS Policy Memoranda 52, 55, 57, 58, 60, Guidelines for Deciding If Review by Human Subjects Review Board is Necessary.

**ATTACHMENT A - Confidentiality Notice to Clients**

The Confidentiality Notice to Clients is maintained by the Divisions. Therefore, Attachment A is not required to be processed or maintained by the NET Contractor.

**ATTACHMENT B – Confidentiality Agreement**

The NET Contractors HIPAA Confidentiality Policy and Procedure Manual meets and exceeds the Department and Divisions requirements contained in Policy Memorandum Number 5 and the Confidentiality Agreement.

Therefore, in lieu of the Department's and Division's Confidentiality Agreement, Attachment B and employee/agent signature affirming assurance of confidentiality and acknowledgment of the Confidentiality Agreement. The NET Contractor shall require Transportation Service Providers to duplicate the NET Contractor's HIPAA Confidentiality Policy and Procedure manual and require all employees (drivers) of the transportation provider to acknowledge receipt of the NET Contractor's HIPAA Confidentiality Policy and Procedure manual and to affix their signature to the signature page. The signed NET Contractor's HIPAA Confidentiality Policy and Procedure manual shall be maintained by the Transportation Service Provider and shall be available for inspection by the NET Contractor, the Department, the Divisions and any other Federal and/or State agency.

SAMPLE OF A CONSENT FOR RELEASE OF
CONFIDENTIAL INFORMATION FORM

_____ of _____
(Requesting Individual) (Service Provider/Program)
_____requests permission from
_____to release certain confidential information
(Client/Guardian)

about . _____This information will be released to:
(client)

Requester's Name: _____ Address:_____
Organization: _____ _____
Position: _____ Phone: _____
Information to be released:
_____
Purp
ose for the information: _____
_____
_____
_____ and _____ must abide by the
(requesting individual) (requesting organization)

following limitations regarding use of the information released:

_____
My signature indicates that I know exactly what information is being disclosed and have had the chance to correct and change the information to make sure it is correct and complete. I am aware that this consent can be revoked in writing at any time.
My signature also means that I have read this form and/or had it read to me and explained in a language I can understand. All blank spaces have been filled in except for signatures and dates.

This consent ends (time period) unless revoked by me in writing before that time. This consent is effective immediately and shall stay in effect as stated.

_____ _____ _____
(Client's signature or "X") (Date signed) (Witness/Date signed)
_____ _____ _____
(Client's guardian, if applicable) (Date signed) (Witness/Date signed)
_____ _____
(Releasing Department/Agency Representative) (Date signed)

# Appendix E

# Title 42: Public Health

PART 455—PROGRAM INTEGRITY: MEDICAID
Subpart B—Disclosure of Information by Providers and Fiscal Agents

## § 455.101 Definitions.

Link to an amendment published at 76 FR 5967, Feb. 2, 2011.

*Agent* means any person who has been delegated the authority to obligate or act on behalf of a provider.

*Disclosing entity* means a Medicaid provider (other than an individual practitioner or group of practitioners), or a fiscal agent.

*Other disclosing entity* means any other Medicaid disclosing entity and any entity that does not participate in Medicaid, but is required to disclose certain ownership and control information because of participation in any of the programs established under title V, XVIII, or XX of the Act. This includes:

(a) Any hospital, skilled nursing facility, home health agency, independent clinical laboratory, renal disease facility, rural health clinic, or health maintenance organization that participates in Medicare (title XVIII);

(b) Any Medicare intermediary or carrier; and

(c) Any entity (other than an individual practitioner or group of practitioners) that furnishes, or arranges for the furnishing of, health-related services for which it claims payment under any plan or program established under title V or title XX of the Act.

*Fiscal agent* means a contractor that processes or pays vendor claims on behalf of the Medicaid agency.

*Group of practitioners* means two or more health care practitioners who practice their profession at a common location (whether or not they share common facilities, common supporting staff, or common equipment).

*Indirect ownership interest* means an ownership interest in an entity that has an ownership interest in the disclosing entity. This term includes an ownership interest in any entity that has an indirect ownership interest in the disclosing entity.

*Managing employee* means a general manager, business manager, administrator, director, or other individual who exercises operational or managerial control over, or who directly or indirectly conducts the day-to-day operation of an institution, organization, or agency.

*Ownership interest* means the possession of equity in the capital, the stock, or the profits of the disclosing entity.

*Person with an ownership or control interest* means a person or corporation that—

(a) Has an ownership interest totaling 5 percent or more in a disclosing entity;

(b) Has an indirect ownership interest equal to 5 percent or more in a disclosing entity;

(c) Has a combination of direct and indirect ownership interests equal to 5 percent or more in a disclosing entity;

(d) Owns an interest of 5 percent or more in any mortgage, deed of trust, note, or other obligation secured by the disclosing entity if that interest equals at least 5 percent of the value of the property or assets of the disclosing entity;

(e) Is an officer or director of a disclosing entity that is organized as a corporation; or

(f) Is a partner in a disclosing entity that is organized as a partnership.

*Significant business transaction* means any business transaction or series of transactions that, during any one fiscal year, exceed the lesser of $25,000 and 5 percent of a provider's total operating expenses.

*Subcontractor* means—

(a) An individual, agency, or organization to which a disclosing entity has contracted or delegated some of its management functions or responsibilities of providing medical care to its patients; or

(b) An individual, agency, or organization with which a fiscal agent has entered into a contract, agreement, purchase order, or lease (or leases of real property) to obtain space, supplies, equipment, or services provided under the Medicaid agreeement.

*Supplier* means an individual, agency, or organization from which a provider purchases goods and services used in carrying out its responsibilities under Medicaid (e.g., a commercial laundry, a manufacturer of hospital beds, or a pharmaceutical firm).

*Wholly owned supplier* means a supplier whose total ownership interest is held by a provider or by a person, persons, or other entity with an ownership or control interest in a provider.

[44 FR 41644, July 17, 1979, as amended at 51 FR 34788, Sept. 30, 1986]

# Amendment(s) published February 2, 2011, in 76 FR 5967

Effective Date(s): March 25, 2011

24. Section 455.101 is amended by adding the definitions of "Health insuring organization (HIO)," "Managed care entity (MCE)," "Prepaid ambulatory health plan (PAHP)," "Prepaid inpatient health plan (PIHP)," "Primary care case manager (PCCM)," and "Termination" in alphabetical order to read as follows:

## § 455.101 Definitions.

*Health insuring organization (HIO)* has the meaning specified in §438.2.

*Managed care entity (MCE)* means managed care organizations (MCOs), PIHPs, PAHPs, PCCMs, and HIOs.

*Prepaid ambulatory health plan (PAHP)* has the meaning specified in §438.2.

*Prepaid inpatient health plan (PIHP)* has the meaning specified in §438.2.

*Primary care case manager (PCCM)* has the meaning specified in §438.2.

*Termination* means—

(1) For a—

(i) Medicaid or CHIP provider, a State Medicaid program or CHIP has taken an action to revoke the provider's billing privileges, and the provider has exhausted all applicable appeal rights or the timeline for appeal has expired; and

(ii) Medicare provider, supplier or eligible professional, the Medicare program has revoked the provider or supplier's billing privileges, and the provider has exhausted all applicable appeal rights or the timeline for appeal has expired.

(2)(i) In all three programs, there is no expectation on the part of the provider or supplier or the State or Medicare program that the revocation is temporary.

(ii) The provider, supplier, or eligible professional will be required to reenroll with the applicable program if they wish billing privileges to be reinstated.

(3) The requirement for termination applies in cases where providers, suppliers, or eligible professionals were terminated or had their billing privileges revoked for cause which may include, but is not limited to—

(i) Fraud;

(ii) Integrity; or

(iii) Quality.

# Title 42: Public Health

## PART 455—PROGRAM INTEGRITY: MEDICAID

View Printed Federal Register page76 FR 5967in PDF format.

# Amendment(s) published February 2, 2011, in 76 FR 5967

Effective Date(s): March 25, 2011

25. Section 455.104 is revised to read as follows:

### § 455.104 Disclosure by Medicaid providers and fiscal agents: Information on ownership and control.

(a) *Who must provide disclosures.* The Medicaid agency must obtain disclosures from disclosing entities, fiscal agents, and managed care entities.

(b) *What disclosures must be provided.* The Medicaid agency must require that disclosing entities, fiscal agents, and managed care entities provide the following disclosures:

(1)(i) The name and address of any person (individual or corporation) with an ownership or control interest in the disclosing entity, fiscal agent, or managed care entity. The address for corporate entities must include as applicable primary business address, every business location, and P.O. Box address.

(ii) Date of birth and Social Security Number (in the case of an individual).

(iii) Other tax identification number (in the case of a corporation) with an ownership or control interest in the disclosing entity (or fiscal agent or managed care entity) or in any subcontractor in which the disclosing entity (or fiscal agent or managed care entity) has a 5 percent or more interest.

(2) Whether the person (individual or corporation) with an ownership or control interest in the disclosing entity (or fiscal agent or managed care entity) is related to another person with ownership or control interest in the disclosing entity as a spouse, parent, child, or sibling; or whether the person (individual or corporation) with an ownership or control interest in any subcontractor in which the disclosing entity (or fiscal agent or managed care entity) has a 5 percent or more interest is related to another person with ownership or control interest in the disclosing entity as a spouse, parent, child, or sibling.

(3) The name of any other disclosing entity (or fiscal agent or managed care entity) in which an owner of the disclosing entity (or fiscal agent or managed care entity) has an ownership or control interest.

(4) The name, address, date of birth, and Social Security Number of any managing employee of the disclosing entity (or fiscal agent or managed care entity).

(c) *When the disclosures must be provided.*

(1) *Disclosures from providers or disclosing entities.* Disclosure from any provider or disclosing entity is due at any of the following times:

(i) Upon the provider or disclosing entity submitting the provider application.

(ii) Upon the provider or disclosing entity executing the provider agreement.

(iii) Upon request of the Medicaid agency during the re-validation of enrollment process under §455.414.

(iv) Within 35 days after any change in ownership of the disclosing entity.

(2) *Disclosures from fiscal agents.* Disclosures from fiscal agents are due at any of the following times:

(i) Upon the fiscal agent submitting the proposal in accordance with the State's procurement process.

(ii) Upon the fiscal agent executing the contract with the State.

(iii) Upon renewal or extension of the contract.

(iv) Within 35 days after any change in ownership of the fiscal agent.

(3) *Disclosures from managed care entities.* Disclosures from managed care entities (MCOs, PIHPs, PAHPs, and HIOs), except PCCMs are due at any of the following times:

(i) Upon the managed care entity submitting the proposal in accordance with the State's procurement process.

(ii) Upon the managed care entity executing the contract with the State.

(iii) Upon renewal or extension of the contract.

(iv) Within 35 days after any change in ownership of the managed care entity.

(4) *Disclosures from PCCMs.* PCCMs will comply with disclosure requirements under paragraph (c)(1) of this section.

(d) *To whom must the disclosures be provided.* All disclosures must be provided to the Medicaid agency.

(e) *Consequences for failure to provide required disclosures.* Federal financial participation (FFP) is not available in payments made to a disclosing entity that fails to disclose ownership or control information as required by this section.

## § 455.105 Disclosure by providers: Information related to business transactions.

(a) *Provider agreements.* A Medicaid agency must enter into an agreement with each provider under which the provider agrees to furnish to it or to the Secretary on request, information related to business transactions in accordance with paragraph (b) of this section.

(b) *Information that must be submitted.* A provider must submit, within 35 days of the date on a request by the Secretary or the Medicaid agency, full and complete information about—

(1) The ownership of any subcontractor with whom the provider has had business transactions totaling more than $25,000 during the 12-month period ending on the date of the request; and

(2) Any significant business transactions between the provider and any wholly owned supplier, or between the provider and any subcontractor, during the 5-year period ending on the date of the request.

(c) *Denial of Federal financial participation (FFP).* (1) FFP is not available in expenditures for services furnished by providers who fail to comply with a request made by the Secretary or the Medicaid agency under paragraph (b) of this section or under §420.205 of this chapter (Medicare requirements for disclosure).

(2) FFP will be denied in expenditures for services furnished during the period beginning on the day following the date the information was due to the Secretary or the Medicaid agency and ending on the day before the date on which the information was supplied.

## § 455.106 Disclosure by providers: Information on persons convicted of crimes.

(a) *Information that must be disclosed.* Before the Medicaid agency enters into or renews a provider agreement, or at any time upon written request by the Medicaid agency, the provider must disclose to the Medicaid agency the identity of any person who:

(1) Has ownership or control interest in the provider, or is an agent or managing employee of the provider; and

(2) Has been convicted of a criminal offense related to that person's involvement in any program under Medicare, Medicaid, or the title XX services program since the inception of those programs.

(b) *Notification to Inspector General.* (1) The Medicaid agency must notify the Inspector General of the Department of any disclosures made under paragraph (a) of this section within 20 working days from the date it receives the information.

(2) The agency must also promptly notify the Inspector General of the Department of any action it takes on the provider's application for participation in the program.

(c) *Denial or termination of provider participation.* (1) The Medicaid agency may refuse to enter into or renew an agreement with a provider if any person who has an ownership or control interest in the provider, or who is an agent or managing employee of the provider, has been convicted of a criminal offense related to that person's involvement in any program established under Medicare, Medicaid or the title XX Services Program.

(2) The Medicaid agency may refuse to enter into or may terminate a provider agreement if it determines that the provider did not fully and accurately make any disclosure required under paragraph (a) of this section.

# Title 42: Public Health

PART 1001—PROGRAM INTEGRITY—MEDICARE AND STATE HEALTH CARE PROGRAMS
Subpart D—Waivers and Effect of Exclusion

Browse Previous

## § 1001.1901 Scope and effect of exclusion.

(a) *Scope of exclusion.* Exclusions of individuals and entities under this title will be from Medicare, Medicaid and any of the other Federal health care programs, as defined in §1001.2.

(b) *Effect of exclusion on excluded individuals and entities.* (1) Unless and until an individual or entity is reinstated into the Medicare, Medicaid and other Federal health care programs in accordance with subpart F of this part, no payment will be made by Medicare, Medicaid or any of the other Federal health care programs for any item or service furnished, on or after the effective date specified in the notice period, by an excluded individual or entity, or at the medical direction or on the prescription of a physician or other authorized individual who is excluded when the person furnishing such item or service knew or had reason to know of the exclusion. This section applies regardless of whether an individual or entity has obtained a program provider number or equivalent, either as an individual or as a member of a group, prior to being reinstated.

(2) An excluded individual or entity may not take assignment of an enrollee's claim on or after the effective date of exclusion.

(3) An excluded individual or entity that submits, or causes to be submitted, claims for items or services furnished during the exclusion period is subject to civil money penalty liability under section 1128A(a)(1)(D) of the Act, and criminal liability under section 1128B(a)(3) of the Act and other provisions. In addition, submitting claims, or causing claims to be submitted or payments to be made for items or services furnished, ordered or prescribed, including administrative and management services or salary, may serve as the basis for denying reinstatement to the programs.

(c) *Exceptions to paragraph (b)(1) of this section.* (1) If an enrollee of Part B of Medicare submits an otherwise payable claim for items or services furnished by an excluded individual or entity, or under the medical direction or on the prescription of an excluded physician or other authorized individual after the effective date of exclusion, CMS will pay the first claim submitted by the enrollee and immediately notify the enrollee of the exclusion.

(2) CMS will not pay an enrollee for items or services furnished by an excluded individual or entity, or under the medical direction or on the prescription of an excluded physician or other authorized individual more than 15 days after the date on the notice to the enrollee, or after the effective date of the exclusion, whichever is later.

(3) Unless the Secretary determines that the health and safety of beneficiaries receiving services under Medicare, Medicaid or any of the other Federal health care programs warrants the exclusion taking effect earlier, payment may be made under such program for up to 30 days after the effective date of the exclusion for—

(i) Inpatient institutional services furnished to an individual who was admitted to an excluded institution before the date of the exclusion,

(ii) Home health services and hospice care furnished to an individual under a plan of care established before the effective date of the exclusion, and

(iii) Any health care items that are ordered by a practitioner, provider or supplier from an excluded manufacturer before the effective date of the exclusion and delivered within 30 days of the effective date of such exclusion. (For the period October 2, 1998, to October 4, 1999, payment may be made under Medicare or a State health care program for up to 60 days after the effective date of the exclusion for any health care items that are ordered by a practitioner, provider or supplier from an excluded manufacturer before the effective date of such exclusion and delivered within 60 days of the effect of the exclusion.)

(4) CMS will not pay any claims submitted by, or for items or services ordered or prescribed by, an excluded provider for dates of service 15 days or more after the notice of the provider's exclusion was mailed to the supplier.

(5)(i) Notwithstanding the other provisions of this section, payment may be made under Medicare, Medicaid or other Federal health care programs for certain emergency items or services furnished by an excluded individual or entity, or at the medical direction or on the prescription of an excluded physician or other authorized individual during the period of exclusion. To be payable, a claim for such emergency items or services must be accompanied by a sworn statement of the person furnishing the items or services specifying the nature of the emergency and why the items or services could not have been furnished by an individual or entity eligible to furnish or order such items or services.

(ii) Notwithstanding paragraph (c)(5)(i) of this section, no claim for emergency items or services will be payable if such items or services were provided by an excluded individual who, through an employment, contractual or any other arrangement, routinely provides emergency health care items or services.

[57 FR 3330, Jan. 29, 1992, as amended at 60 FR 32917, June 26, 1995; 63 FR 46690, Sept. 2, 1998; 64 FR 39427, July 22, 1999]

**Appendix G**

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850
Center for Medicaid and State Operations
SMDL #08-003
June 12, 2008
Dear State Medicaid Director:
The Centers for Medicare & Medicaid Services (CMS) is issuing this State Medicaid Director Letter to strengthen the integrity of the Medicaid program and help States reduce improper payments to providers. This letter specifically:
(1) Clarifies CMS policy with respect to States' obligations to screen for excluded individuals and entities prior to and during provider enrollment;
(2) Reminds States of the obligation to report to the Health and Human Service Office of Inspector General (OIG) both convictions related to the Medicaid program and sanctions imposed by the State Medicaid Agency on Medicaid providers; and
(3) Reminds States of the consequences set forth in Federal laws and regulations for failure to prevent Medicaid participation by excluded individuals and entities.

**Background**

The OIG excludes individuals and entities from participation in Medicare, Medicaid, the State Children's Health Insurance Program (SCHIP), and all Federal health care programs (as defined in section 1128B(f) of the Social Security Act (the Act)) based on the authority contained in various sections of the Act, including sections 1128, 1128A, 1156, and 1892.
When the OIG has excluded a provider, Federal health care programs (including Medicaid and SCHIP programs) are prohibited from paying for any items or services furnished, ordered, or prescribed by excluded individuals or entities until the provider has been reinstated by the OIG (42 CFR section 1001.1901). The only exception is when the OIG has waived the exclusion of an individual or entity. *See* sections 1128(c)(3)(B) and 1128(d)(3)(B) of the Act; and 42 CFR section 1001.1801. No State may waive such an exclusion, in whole or in part. Only the OIG has the authority to waive an exclusion that it has imposed. If a State believes that waiver of an exclusion is appropriate, it may submit a written request for such a waiver to the OIG (42 CFR section 1001.1801).
Additionally, section 1932(d)(1) of the Act prohibits managed care organizations (MCOs) and primary care case managers (PCCMs) from knowingly having a director, officer, partner, or person with a beneficial ownership of more than 5 percent of the entity's equity who is debarred, suspended, or excluded, or from having an employment, consulting, or other agreement with an

individual or entity for the provision of items and services that are significant and material to the entity's obligations under its contract with the State where the individual or entity is debarred, suspended, or excluded. Section 438.610 of the Federal managed care regulations extends the prohibition to prepaid inpatient health plans (PIHPs) and prepaid ambulatory health plans (PAHPs) (42 CFR section 438.610.) If a State finds that

an MCO, PCCM, PIHP, or PAHP has a noncompliant relationship, the State must notify the Secretary of the noncompliance. The State may not renew or extend its agreement with the noncompliant entity unless the Secretary provides to the State and to Congress a written statement describing compelling reasons to renew or extend the agreement. Additional administrative sanctions applicable to MCEs are set forth in 42 CFR section 438.700 *et seq.*

**Policy Clarification**

States must determine whether current providers, managed care entities (MCEs) (i.e., MCOs, PCCMs, PIHPs, and PAHPs),* providers applying to participate in the Medicaid program, and individuals with an ownership or control interest in the provider entity or MCE are excluded individuals or entities. Since Federal regulations prohibit payment for items or services furnished by excluded individuals and entities, it is imperative that this first line of defense in combating fraud and abuse be conducted accurately, thoroughly, and routinely.

**Previous Guidance**

In a State Medicaid Director Letter issued on March 17, 1999, and in a follow-up State Medicaid Director Letter issued on May 16, 2000, CMS described the OIG's authority to exclude persons based on actions taken by State Medicaid Agencies.

In the State Medicaid Director Letter dated May 16, 2000, CMS reminded States that the Medicare/Medicaid Sanction-Reinstatement Report, formerly known as HCFA Publication 69 and now replaced by the Medicare Exclusion Database, discussed below, is a vital resource for ascertaining and verifying whether a provider is excluded and should not be receiving payments. The guidance also stated that the payment prohibition applies to any MCO contracting with an excluded party.

**State Obligations Concerning Excluded Individuals and Entities**

Federal statutes and regulations clearly prohibit States from paying for items or services furnished, ordered or prescribed by excluded persons. States typically do screen for excluded providers prior to and after enrollment. However, not all States attempt to determine whether an excluded individual has an ownership or control interest, as defined below, in an entity that is a Medicaid provider. Federal regulations at 42 CFR section 1002.3 require States to report to OIG information regarding individuals that have ownership or control interests in provider entities and who have been convicted of a criminal offense as described in sections 1128(a) and 1128(b)(1), (2), or (3) of the Act, that have had civil monetary penalties imposed under section 1128A of the Act, or that have been excluded from participation in Medicare or any of the State

* While this *State Medicaid Director Letter* uses the term "managed care entity" to refer briefly to MCOs, PIHPs, PAHPs, and PCCMs, States should not confuse this abbreviation with the statutory definition of managed care entity which only refers to MCOs and PCCMs. *See* section 1932(a)(1)(B) of the Act.



health care programs, within 20 business days after the date the agency receives the information. If appropriate, OIG may permissively exclude the provider under section 1128(b)(8) of the Act and under 42 CFR section 1001.1001.

***General Rules***

• States should solicit information from providers about individuals with ownership or control interests in the provider entity.

• In accordance with the rules set forth in this letter, States should search the Medicare Exclusion Database (MED) or the OIG List of Excluded Individuals/Entities (LEIE) database by the names of any individual, entity, or individual with ownership or control interest in any provider entity providing services for which payment is made under the Medicaid program or seeking to participate in the Medicaid program, including through a fee-for-service delivery system or through the State's managed care program or other waiver program.
• States should review provider enrollment eligibility upon enrollment or reenrollment.
• States should search the MED or the OIG Web site monthly to capture exclusions and reinstatements that have occurred since the last search.
• States should search the exclusions database for both in-State providers and out-of-State providers seeking to participate in the program.
• States should not process a provider's disclosure information that does not appear complete or does not include information on individuals with ownership or control interests in the provider entity, including managing employees, until the State verifies the accuracy and completeness of the information.
• States should report to OIG any exclusion information that is disclosed to them by a provider about an individual who has or had an ownership or control interest in a provider entity or who is a managing employee of a provider entity within 20 business days after receipt of such information.
• States must notify the OIG promptly if the State Medicaid Agency has taken any action on the provider's application for participation in the Medicaid program.
• States should notify the OIG promptly of any administrative action the State takes to limit a provider's participation in the Medicaid program that might lead to an exclusion.

*Ownership and Control Interests*

An individual is considered to have an ownership or control interest in a provider entity if it has direct or indirect ownership of 5 percent or more, or is a managing employee (e.g., a general manager, business manager, administrator, or director) who exercises operational or managerial control over the entity, or who directly or indirectly conducts the day-to-day operations of the entity as defined in section 1126(b) of the Act and under 42 CFR section 1001.1001(a)(1).

States must actively solicit information regarding individuals with ownership or control interests in provider entities from providers because providers may not independently disclose the identity of owners or managing employees on the disclosure document. State data files should capture these important data elements so that an automated comparison of exclusions against a provider file that includes the names of individuals with ownership or control interests in provider entities



can be accomplished easily during regular monthly searches and at any time providers submit new disclosure information to the State. While States may delegate many provider enrollment or credentialing functions to MCEs for the managed care program and to the States' contractors for Home and Community-Based Services (HCBS) and other waiver programs, the State remains responsible for ensuring that it does not pay an excluded provider for Medicaid health care items or services. States that delegate managed care and waiver program provider enrollment and credentialing to their MCEs and HCBS

waiver contractors must mandate that the MCEs and HCBS waiver contractors search the exclusions database with the same frequency as the State for fee-for-service providers. MCEs and HCBS waiver contractors should search for providers, provider entities, and individuals with ownership or control interests in the provider entities.

Under Federal regulations at 42 CFR section 1002.3(a), providers entering into or renewing a provider agreement must disclose to the State Medicaid Agency the identity of any excluded individual with an ownership or control interest in the provider entity. The State Medicaid Agency then must notify the OIG of this information within 20 business days after the date the agency receives the information and must notify the OIG promptly if the State Medicaid Agency has taken any action on the provider's application for participation in the Medicaid program. 42 CFR section 1002.3 (b)(2). The OIG, in its discretion and under statutory and regulatory authority, may exclude that entity.

***Convictions and Administrative Sanctions***

Under 42 CFR section 1002.230, each State, either through its State Medicaid Agency or its Medicaid Fraud Control Unit (MFCU), must notify the OIG of convictions related to the delivery of items or services under the Medicaid program within 15 days after the conviction if the State agency was involved in the investigation or prosecution of the case, or within 15 days after the State agency learns of the conviction if the agency was not involved in the investigation or prosecution of the case. Such a report should include all the necessary documentation to support an exclusion action by the OIG.

Additionally, under 42 CFR section 1002.3, the State agency must notify the OIG of any disclosures made by providers with regard to the ownership or control by a person that has been convicted of a criminal offense described under sections 1128(a) and 1128(b)(1), (2), or (3) of the Act, or that has had civil money penalties or assessments imposed under section 1128A of the Act. *See* 42 CFR section 1001.1001(a)(1). The State Medicaid Agency must notify the OIG of this information within 20 business days after the date it receives the information. 42 CFR sections 455.106(b)(1) and 1002.3.

States are required under 42 CFR sections 455.106(b)(2) and 1002.3(b)(3) to notify the OIG promptly of any administrative action it takes to limit participation of a provider in the Medicaid program. Reporting these criminal and administrative actions is critical to timely implementation of exclusions of persons who have defrauded health care programs or harmed patients. Currently in some States there are significant delays in reporting of such actions. Such



delays jeopardize the government's ability to protect the Federal health care programs and their beneficiaries from untrustworthy persons.

**Where to Look for Excluded Parties**

***Medicare Exclusion Database***

In 2002, HCFA Publication 69 was replaced by a new system of record called the Medicare Exclusion Database (MED). The MED was developed to collect and retrieve information that aided in ensuring that no payments are made to excluded individuals and entities for services furnished during the exclusion period. Two of the information sources used in populating the MED are the OIG Exclusion file and the Social Security Administration. MED files contain a variety of identifiable and general information including name, Social Security Number (SSN), employer identification number, Uniform Provider Identification Number, National Provider Identifier, address, exclusion

type, and reinstatement date, if applicable. The five MED files are e-mailed to States every month. These files contain the month's new exclusions, new reinstatements, cumulative exclusions, cumulative reinstatements and non-MED data. MED files are also available through CMS' Application Portal.

***List of Excluded Individuals/Entities***

The OIG maintains the LEIE, a database that provides information about parties excluded from participation in Medicare, Medicaid, and all other Federal health care programs. The LEIE Web site is located at http://oig.hhs.gov/fraud/exclusions/listofexcluded.html and is available in two formats. The on-line search engine identifies currently excluded individuals or entities. When a match is identified, it is possible for the searcher to verify the accuracy of the match using a SSN or Employer Identification Number (EIN). The downloadable version of the database may be compared against State enrollment files. However, unlike the on-line format, the downloadable database does not contain SSNs or EINs.

**When to Look for Excluded Parties**

States should review provider enrollment eligibility whenever an individual or entity submits an application for enrollment or reenrollment in the program. Additionally, States should conduct searches on both in-State providers and out-of-State providers about which the State Medicaid Agency would not have received notice of exclusion. States should conduct the searches monthly via the MED or the OIG Web site to capture exclusions and reinstatements that have occurred since the last search.

**Reminder of Consequences of Paying Excluded Providers**

The CMS informed States in the State Medicaid Director Letter dated May 16, 2000, that under section 1903(i)(2) of the Act CMS shall make no payments to States for any amount expended for items or services (other than an emergency item or service not provided in a hospital emergency room) furnished under the plan by an individual or entity while being excluded from participation. This includes Medicare, Medicaid, SCHIP, and all Federal health care programs (as defined in section 1128B(f) of the Act) based on the authority contained in various sections of the Act, including sections 1128, 1128A, 1156, and 1892. Any such payments actually



claimed for Federal financial participation (FFP) constitute an overpayment under section 1903(d)(2)(A) of the Act and are unallowable for FFP.

Further, States may not seek Federal reimbursement for payments to providers that have not provided required ownership and control disclosures, or other disclosures regarding business transactions, under 42 CFR sections 455.104 and 455.105. States may deny enrollment to a provider whose owner, agent, or managing employee has been convicted of a criminal offense relating to Medicare, Medicaid, or title XX programs. Moreover, States may deny enrollment or terminate a provider's enrollment if the State determines the provider did not fully disclose required criminal conviction information, under 42 CFR section 455.106(c).

**Conclusion**

We know you share our commitment to combating fraud and abuse and understand that provider enrollment is the first line of defense in this endeavor. If we strengthen our efforts to identify excluded parties, the integrity and quality of the Medicaid program will be improved, benefiting Medicaid beneficiaries and taxpayers across the country.

If you have any questions or would like any additional information on this guidance, please direct your inquiries to Ms. Claudia Simonson, Centers for Medicare & Medicaid Services, Center for Medicaid and State Operations, Medicaid Integrity Group, Division of Field Operations, 233 North Michigan Avenue, Suite 600, Chicago, IL 60601 or claudia.simonson@cms.hhs.gov. Thank you for your assistance in this important endeavor.

Sincerely,

/s/

Herb B. Kuhn
Deputy Administrator
Acting Director, Center for Medicaid and State Operations

cc:
CMS Regional Administrators
CMS Associate Regional Administrators
Division of Medicaid and Children's Health
Barbara Edwards
NASMD Interim Director
American Public Human Services Association
Joy Wilson
Director, Health Committee
National Conference of State Legislatures
Page 7 – State Medicaid Director
Matt Salo
Director of Health Legislation
National Governors Association
Debra Miller
Director for Health Policy
Council of State Governments
Christie Raniszewski Herrera
Director, Health and Human Services Task Force
American Legislative Exchange Council
Barbara Levine
Director of Policy and Programs
Association of State and Territorial Health Officials

**Appendix H**

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850
Center for Medicaid and State Operations
SMDL #09-001
January 16, 2009
Dear State Medicaid Director:
The Center for Medicaid and State Operations (CMSO) is issuing this State Medicaid Director Letter to strengthen the integrity of the Medicaid program and help States reduce improper payments to providers. This letter advises States of their obligation to direct providers to screen their own employees and contractors for excluded persons. This letter specifically:
(1) Clarifies Federal statutory and regulatory prohibitions regarding Medicaid payments for any items or services furnished or ordered by individuals or entities that have been excluded from participation in Federal health care programs;
(2) Reminds States of the consequences for failure to prevent payments for items or services furnished or ordered by excluded individuals and entities;
(3) Sets forth the Centers for Medicare & Medicaid Services' (CMS) policy with respect to States' responsibility to communicate to providers their obligation to screen employees and contractors for excluded individuals and entities both prior to hiring or contracting and on a periodic basis, and the manner in which overpayment calculations should be made; and
(4) Identifies the List of Excluded Individuals/Entities (LEIE) as a resource providers may utilize to determine whether any of their employees and contractors has been excluded.

**Background**

The HHS Office of Inspector General (HHS-OIG) excludes individuals and entities from participation in Medicare, Medicaid, the State Children's Health Insurance Program (SCHIP), and all Federal health care programs (as defined in section 1128B(f) of the Social Security Act (the Act)) based on the authority contained in various sections of the Act, including sections 1128, 1128A, and 1156.
When the HHS-OIG has excluded a provider, Federal health care programs (including Medicaid and SCHIP programs) are generally prohibited from paying for any items or services furnished, ordered, or prescribed by excluded individuals or entities. (Section 1903(i)(2) of the Act; and 42 CFR section 1001.1901(b)) This payment ban applies to any items or services reimbursable under a Medicaid program that are furnished by an excluded individual or entity, and extends to:


all methods of reimbursement, whether payment results from itemized claims, cost reports, fee schedules, or a prospective payment system;

payment for administrative and management services not directly related to patient care, but that are a necessary component of providing items and services to

Medicaid recipients, when those payments are reported on a cost report or are otherwise payable by the Medicaid program; and

payment to cover an excluded individual's salary, expenses or fringe benefits, regardless of whether they provide direct patient care, when those payments are reported on a cost report or are otherwise payable by the Medicaid program.

In addition, no Medicaid payments can be made for any items or services directed or prescribed by an excluded physician or other authorized person when the individual or entity furnishing the services either knew or should have known of the exclusion. This prohibition applies even when the Medicaid payment itself is made to another provider, practitioner or supplier that is not excluded. (42 CFR section 1001.1901(b))
The listing below sets forth some examples of types of items or services that are reimbursed by Medicaid which, when provided by excluded parties, are not reimbursable*:

Services performed by excluded nurses, technicians, or other excluded individuals who work for a hospital, nursing home, home health agency or physician practice, where such services are related to administrative duties, preparation of surgical trays or review of treatment plans if such services are reimbursed directly or indirectly (such as through a pay per service or a bundled payment) by a Medicaid program, even if the individuals do not furnish direct care to Medicaid recipients;

Services performed by excluded pharmacists or other excluded individuals who input prescription information for pharmacy billing or who are involved in any way in filling prescriptions for drugs reimbursed, directly or indirectly, by a Medicaid program;

Services performed by excluded ambulance drivers, dispatchers and other employees involved in providing transportation reimbursed by a Medicaid program, to hospital patients or nursing home residents;

Services performed for program recipients by excluded individuals who sell, deliver or refill orders for medical devices or equipment being reimbursed by a Medicaid program;

Services performed by excluded social workers who are employed by health care entities to provide services to Medicaid recipients, and whose services are reimbursed, directly or indirectly, by a Medicaid program;

Services performed by an excluded administrator, billing agent, accountant, claims processor or utilization reviewer that are related to and reimbursed, directly or indirectly, by a Medicaid program;

* This list is drawn from the 1999 HHS-OIG Special Advisory Bulletin: The Effect of Exclusion From Participation in Federal Health Care Programs.



Items or services provided to a Medicaid recipient by an excluded individual who works for an entity that has a contractual agreement with, and is paid by, a Medicaid program; and

Items or equipment sold by an excluded manufacturer or supplier, used in the care or treatment of recipients and reimbursed, directly or indirectly, by a Medicaid program.

**Consequences to States of Paying Excluded Providers**

Because it is prohibited by Federal law from doing so, CMS shall make no payments to States for any amount expended for items or services (other than an emergency item or service not provided in a hospital emergency room) furnished under the plan by an individual or entity while being excluded from participation (unless the claim for payment meets an exception listed in 42 CFR section 1001.1901(c)). Any such payments actually claimed for Federal financial participation constitute an overpayment under sections 1903(d)(2)(A) and 1903(i)(2) of the Act, and are therefore subject to recoupment. It is thus incumbent on States to take all reasonable steps to prevent making payments that must ultimately be refunded to CMS.

**Previous Guidance Regarding Preventing Payments For Goods and Services Furnished by Excluded Individuals and Entities**

In a State Medicaid Director Letter issued on June 12, 2008, CMS notified States of their own obligation to attempt to determine whether an excluded individual has an ownership or control interest in an entity that is a Medicaid provider, and of States' obligation to report information regarding such excluded individuals to the HHS-OIG. In a State Medicaid Director Letter issued on March 17, 1999, and in a follow-up State Medicaid Director Letter issued on May 16, 2000 ("Medicare/Medicaid Sanction Reinstatement Report"), CMS described the HHS-OIG's authority to exclude persons based on actions taken by State Medicaid Agencies.

In the State Medicaid Director Letter dated May 16, 2000, CMS reminded States that the Medicare/Medicaid Sanction-Reinstatement Report, formerly known as HCFA Publication 69 and now replaced by the Medicare Exclusion Database (the MED) is a vital resource available to States for ascertaining and verifying whether an individual or entity is excluded and should not be receiving payments. The guidance also stated that the payment prohibition applies to any managed care organization contracting with an excluded party.

In a second State Medicaid Director Letter dated May 16, 2000 ("State's Obligation to notify the Department of Health and Human Services Office of Inspector General"), CMS reminded States of their responsibility to promptly notify the HHS-OIG of any action taken by a State to limit the ability of an individual or entity to participate in its program. *See* 42 CFR section 1002.3(b)(3).

† This State Medicaid Director Letter uses the term "managed care entity" to refer briefly to managed care organizations (MCOs), prepaid inpatient health plans, prepaid ambulatory health plans, and primary care case management (PCCM). States should not

confuse this abbreviation with the statutory definition of managed care entity which only refers to MCOs and PCCMs. *See* section 1932(a)(1)(B) of the Act.



**Policy Clarification: States Should Advise Medicaid Providers to Screen for Exclusions**

To further protect against payments for items and services furnished or ordered by excluded parties, States should advise all current providers and providers applying to participate in the Medicaid program to take the following steps to determine whether their employees and contractors are excluded individuals or entities:

States should advise providers of their obligation to screen all employees and contractors to determine whether any of them have been excluded. States should communicate this obligation to providers upon enrollment and reenrollment.

States should explicitly require providers to agree to comply with this obligation as a condition of enrollment.

States should inform providers that they can search the HHS-OIG website by the names of any individual or entity.

States should require providers to search the HHS-OIG website monthly to capture exclusions and reinstatements that have occurred since the last search.

States should require that providers immediately report to them any exclusion information discovered.

This line of defense in combating fraud and abuse must be conducted accurately, thoroughly, and routinely. States must notify the HHS-OIG promptly of any administrative action the State takes against a provider for failure to comply with these screening and reporting obligations. *See* 42 CFR section 1002.3(b)(3). States can satisfy this obligation by communicating the relevant information to the appropriate Regional Office of the OIG Office of Investigations.

States also should inform providers that civil monetary penalties may be imposed against Medicaid providers and managed care entities (MCEs)† who employ or enter into contracts with excluded individuals or entities to provide items or services to Medicaid recipients. (Section 1128A(a)(6) of the Act; and 42 CFR section 1003.102(a)(2))

**Policy Clarification: Calculation of Overpayments to Excluded Individuals or Entities**

As stated above, Federal health care programs, including Medicaid, are generally prohibited from paying for any items or services furnished, ordered, or prescribed by excluded individuals or entities. The amount of the Medicaid overpayment for such items or services is the actual amount of Medicaid dollars that were expended for those items or services. When Medicaid funds have been expended to pay an excluded individual's salary, expenses, or fringe benefits, the amount of the overpayment is the amount of those expended Medicaid funds. We recognize that there may be instances when the connection between expended Medicaid funds and the

items or services furnished by the excluded individual or entity are too attenuated to trace. When such circumstances arise, the overpayment is no more than the amount which the State is certain was paid with Medicaid dollars.

**Where Providers Can Look for Excluded Parties**

While the MED is not readily available to providers, the HHS-OIG maintains the LEIE, a database accessible to the general public that provides information about parties excluded from participation in Medicare, Medicaid, and all other Federal health care programs. The LEIE website is located at http://www.oig.hhs.gov/fraud/exclusions.asp and is available in two formats. The on-line search engine identifies currently excluded individuals or entities. When a match is identified, it is possible for the searcher to verify the accuracy of the match using a Social Security Number (SSN) or Employer Identification Number (EIN). The downloadable version of the database may be compared against an existing database maintained by a provider. However, unlike the on-line format, the downloadable database does not contain SSNs or EINs.

Additionally, some States maintain their own exclusion lists, pursuant to 42 CFR section 1002.210 or State authority, which include individuals and entities whom the State has barred from participating in State government programs. States with such lists should remind providers that they are obligated to search their State list routinely whenever they search the LEIE.

**Conclusion**

We know you share our commitment to combating fraud and abuse. We all understand that provider enrollment is the first line of defense in this endeavor. If we strengthen our efforts to identify excluded parties, the integrity and quality of the Medicaid program will be improved, benefiting Medicaid recipients and taxpayers across the country.

If you have any questions or would like any additional information on this guidance, please direct your inquiries to Ms. Claudia Simonson, Centers for Medicare & Medicaid Services, Center for Medicaid and State Operations, Medicaid Integrity Group, 233 North Michigan Avenue, Suite 600, Chicago, Illinois 60601 or claudia.simonson@cms.hhs.gov.

Thank you for your assistance in this important endeavor.

Sincerely,

/s/

Herb B. Kuhn
Deputy Administrator
Acting Director, Center for Medicaid and State Operations



cc:
CMS Regional Administrators
CMS Associate Regional Administrators
Division of Medicaid and Children's Health
Ann C. Kohler
NASMD Executive Director
American Public Human Services Association
Joy Wilson
Director, Health Committee
National Conference of State Legislatures

**Appendix I**

STATE OF DELAWARE
DEPARTMENT OF HEALTH AND SOCIAL SERVICES
Division of Medicaid and Medical Assistance

## INSTRUCTIONS FOR COMPLETING DISCLOSURE OF OWNERSHIP AND CONTROL INTEREST STATEMENT

These instructions are designed to clarify certain questions on the licensure form. Instructions are listed in question order for easy reference. No instructions have been given for questions considered self-explanatory.

IT IS ESSENTIAL THAT ALL APPLICABLE QUESTIONS BE ANSWERED ACCURATELY AND THAT ALL INFORMATION IS CURRENT.

**Item A** – Under identifying information, specify in what capacity the entity is doing business as (DBA), example, name of trade or corporation.
Please answer all questions as of the current date. If the Yes block for any item is checked, list requested additional information under Remarks on Page 2, referencing the item. If additional space is needed, use an attached sheet.
**Item C** – List the names of all individuals and organizations having direct or indirect ownership interests, or controlling interest separately or in combination, amounting to an ownership interest of five percent (5%) or more in the disclosing entity.
Direct ownership interest is defined as the possession of stock, equity in capital or any interest in the profits of the disclosing entity. A disclosing entity is defined as a Medicare provider or supplier, or other entity that furnishes services or arranges for furnishing services under Medicaid or the Maternal and Child Health program, or health related services under the social services program. Indirect ownership interest is defined as ownership interest in an entity that has direct or indirect ownership interest in the disclosing entity. The amount of indirect ownership in the disclosing entity that is held by any other entity is determined by multiplying the percentage of ownership interest at each level. An indirect ownership interest must be reported if it equates to an ownership interest of 5 percent or more in the disclosing entity. Example: if A owns 10 percent of the stock in a corporation that owns 80 percent of the stock of the disclosing entity, A's interest equates to an 8 percent indirect ownership and must be reported.
Controlling interest is defined as the operational direction or management of a disclosing entity which may be maintained by any or all of the following devices: the ability or authority, expressed or reserved, to amend or change the corporate identity (i.e., joint venture agreement, unincorporated business status) of the disclosing entity; the ability or authority to nominate or name members of the Board of Directors or Trustees of the disclosing entity; the ability or authority expressed or reserved, to amend or change the by-laws, constitution or other operating or management direction of the disclosing entity; the right to control any or all of the assets or other property of the disclosing entity upon the sale or dissolution of that entity; the ability or authority, expressed or reserved to control the sale of any or all of the assets, to encumber such assets by way of mortgage or other indebtedness, to dissolve the entity, or to arrange for the sale or transfer of the disclosing entity to a new ownership or control.

**Item F - I** –
Change in provider status is defined as any change in management control. Examples of such changes would include: A change in Medical or Nursing Director, a new Administrator, contracting the operation of the facility to a management corporation, a change in the composition of the owning partnership which under applicable State law is not considered a change in ownership, or the hiring or dismissing of any employees with 5 percent or more financial interest in the facility or in an owning corporation, or any changes of ownership.
If the Yes box is checked, list additional information requested under Remarks. Clearly identify which item is being continued.
**Item G** – If the answer is Yes, list name of the management firm and employer identification number (EIN), or the name of the leasing organization. A management company is defined as any organization that operates and manages a business on behalf of the owner of that business, with the owner retaining ultimate legal responsibility for operation of the facility.
**Item H** – If the answer is Yes, identify which has changed (Administrator, Medical Director,
or Director of Nursing) and the date the change was made. Be sure to include the name of the new Administrator, Director of Nursing or Medical Director, as appropriate.
**Item I** – A chain affiliate is any free-standing health care facility that is either owned, controlled or operated under lease or contract by an organization consisting of two or more freestanding health care facilities organized within or across State lines which is under the ownership, or through any other device, control and direction of a common party. Chain affiliates include such facilities whether public, private, charitable or proprietary. They also include subsidiary organizations and holding corporations. Provider based facilities, such as hospital-based home health care agencies, are not considered to be chain affiliates.

**Appendix I**

**STATE OF DELAWARE**
**DEPARTMENT OF HEALTH & SOCIAL SERVICES**
**DIVISION OF MEDICAID AND MEDICAL ASSISSTANCE**
**Disclosure of Ownership and Control Interest Statement**

A. Identifying Information

Name of Entity D/B/A Telephone No.

Street Address City, County, State Zip Code

B. Answer the following questions by checking "Yes" or "No." If any of the questions are answered "yes," list names and addresses of individuals or corporations under Remarks on Page 2. Identify each item number to be continued.

1. Are there any individuals or organizations having a direct or indirect ownership or control interest of 5% or more in the institution, organizations, or agency that have been convicted of a criminal offense related to the involvement of such persons, or organizations in any of the programs established by Titles XVIII, XIX, or XX?

Yes ___ No ___

2. Are there any directors, officers, agents, or managing employees of the institution, agency, or organization who have ever been convicted of a criminal offense related to their involvement in such programs established by Titles XVIII, XIX, or XX?

Yes ___ No ___

C. List names and addresses for individuals, or the EIN for organizations having direct or indirect ownership or a controlling interest in the entity. List any additional names and addresses under Remarks on. If more than one individual is reported and any of these persons are related to each other, this must be reported under Remarks.

Name Address EIN

D. Type of Entity: ___ Sole Proprietorship ___ Partnership ___ Corporation
___ Unincorporated Associations ___ Other

E. Check the appropriate box for each of the following questions.

1. Are any owners of the disclosing entity also owners of other Medicare/Medicaid facilities? (Examples: sole proprietor, partnership, or members of Board of Directors)?

Yes ___ No ___

Facility Name Address Facility NPI

F. Has there been a change in ownership within the last year? Yes ___ No ___
If yes, give date. _____

Do you anticipate any change of ownership or control within the year? Yes ___ No ___
If yes, when? _____

G. Is this facility operated by a management company or leased in whole or in part by another organization? Yes ___ No ___
If yes, give date of change in operations. _____

H. Has there been a change in Administrator, Director of Nursing, or Medical Director within the past year? Yes ___ No ___

I. Is this facility chain-affiliated? If yes, list the name, address, and EIN of the corporation.
Yes ___ No ___

Name EIN

Address

If the answer to the above question is no, was the facility ever affiliated with a chain? If yes, list the name, address, and EIN of the corporation
Yes ___ No ___

Name EIN
Address_____

**Whoever knowingly and willfully makes or causes to be made a false statement or representation of this statement, may be prosecuted under applicable federal or State laws. In addition, knowingly and willfully failing to fully and accurately disclose the information requested may result in denial of a request to participate or, where the entity already participates, a termination of its agreement or contract with the State agency.**

_____

Name of Authorized Representative (Typed) Title

_____

Signature Date

_____

**REMARKS (Continue as needed.)**